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PATENT

Attorney Docket No. VISX-001/00US

#14

Express Mail Label Number: TB854161869US

Date of Deposit: November 27, 1995

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Date: 11-27-95 By: Jason Stang

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	U.S. Patent No. 4,718,418	)	Shay
Issued:	January 12, 1988	)	Examiner: ~~Lee S. Cohen~~
To:	Francis A. L'Esperance, Jr.	)	Art Unit: Not Assigned 3309
Serial No.	06/916,646	)	TRANSMITTAL FOR APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. 156
Filed:	October 8, 1986	)	
For:	APPARATUS FOR OPHTHALMOLOGICAL SURGERY	)	Palo Alto, CA 94306

RECEIVED
DEC 28 1995
GROUP 3300

Assistant Commissioner for Patents
Washington, D.C. 20231
Attn: **Box Patent Ext.**

Sir:

Transmitted herewith is an Application for Extension of Patent Term Under 35 U.S.C. 156.

Also enclosed:

320 GD 12/27/95 08916646
1 115 1 1060.00 CK

[X] An additional copy of the above-mentioned application.

21016974

[X] Requisite fee for Extension of Patent Term ($1060.00).

TOTAL FEES: $1060.00

[X] A check including the amount of the above indicated TOTAL FEES is attached.

[X] Conditional Petition for Extension of Time: An extension of time is requested to provide for timely filing if an extension of time is still required after all papers filed with this transmittal have been considered.

[X] The Commissioner is hereby authorized to charge any underpayment of the following fees associated with this communication, including any necessary fees for extension of time, or credit any overpayment to Deposit Account No. 03-3117:

[X] Any filing fees under 37 CFR 1.16 including fees for the presentation of extra claims.

[X] Any patent application processing fees under 37 CFR 1.17.

A **duplicate** copy of this sheet is attached for accounting purposes.

Respectfully submitted,

COOLEY GODWARD CASTRO
HUDDLESON & TATUM

By: Tom M. Moran
Tom M. Moran
Reg. No. 26,314

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PATENT

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Date: 11-27-95 By: Jason Stamp

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	U.S. Patent No. 4,718,418	
Issued:	January 12, 1988	Examiner: Lee S. Cohen
To:	Francis A. L'Esperance, Jr.	Art Unit: Not Assigned
Serial No.:	06/916,646	
Filed:	October 8, 1986	APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. 156
For:	APPARATUS FOR OPHTHALMOLOGICAL SURGERY	Palo Alto, CA 94306

Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

Sir:

Applicant, VISX, Incorporated ("VISX"), a corporation of the State of Delaware (and formerly known as Taunton Technologies, Inc.), represents that it is the assignee of the entire interest in and to letters patent of the United States Patent No. 4,718,418 granted to Francis A. L'Esperance, Jr. on October 8, 1986 for Apparatus for Ophthalmological

Surgery, by virtue of an assignment in favor of VISX, Incorporated recorded on November 13, 1991, at Reel 5913, Frames 521-523.

Applicant submits this Application for extension of the patent term for U.S. Patent No. 4,718,418 by providing the following information, as required by 35 USC 156 and 37 CFR 1.710 *et seq.* For the convenience of the Patent and Trademark Office, the information contained in this application will be organized corresponding to 37 CFR 1.740.

(1) The approved product is identified as the VISX Excimer Laser System for use in the performance of phototherapeutic keratectomy (PTK). It comprises a fully integrated apparatus that enables an ophthalmologist to perform PTK on patients who choose and can benefit from such treatment to improve their visual acuity. The apparatus employs, *i.a.*, a laser source with a means to adjust laser beam-exposure flux to a level at which corneal tissue can be ablated to a predetermined maximum depth. The fully-integrated apparatus includes an excimer laser, a delivery system, an operating microscope, a patient chair, a debris evacuator, a control panel, a video monitoring system, a laser gas purifier, a system scrubber, a gas supply cabinet and a computer workstation that presently employs VisionKey® 4.10 software.

(2) The VISX Excimer Laser System was subject to regulatory review under Section 515 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(e)).

(3) VISX received permission for commercial marketing under Section 515 of the Federal Food, Drug and Cosmetic Act on September 29, 1995.

(4) This product has not been previously approved for commercial marketing under Section 515 of the Food, Drug and Cosmetic Act.

(5) This Application for extension of the patent term under 35 USC 156 is being submitted within the permitted 60 day period pursuant to 37 CFR 1.720(f); said period will expire on November 28, 1995.

(6) The patent for which patent term extension is sought is U.S. Patent No. 4,718,418, which issued on January 12, 1988 on U.S. Serial No. 06/916,646, filed October 8, 1986, naming Francis A. L'Esperance, Jr. as the inventor, for Apparatus for Ophthalmological Surgery. The term of U.S. Patent No. 4,718,418 has never been extended and has not yet expired. No other patent's terms has been extended for the same regulatory review period for any product.

(7) A complete copy of the U.S. Patent No. 4,718,418 is appended as Attachment "A" hereto.

(8) There has been no disclaimer, or certificate of correction with regard to U.S. Patent No. 4,718,418. The most recent maintenance fee for U.S. Patent No. 4,718,418 has been paid as evidenced by the letter dated 14 AUG 1995 and the receipt for payment of the maintenance fee, a copy both being appended as Attachment "B" hereto.

(9) U.S. Patent No. 4,718,418 claims the approved product in the following claims:

8-16, 26 and 29.

(10) The relevant dates and information pursuant to 35 USC 156(g)(3)(B) are as follows:

(a) August 4, 1989 - Effective date of Investigational Device Exemption (IDE)# G890122 for Phototherapeutic Keratectomy ("PTK"), which is the date a clinical investigation on humans involving the PTK device was begun.

(b) October 15, 1991 - Date an application for premarketing approval (PMA #910062) was initially submitted to the FDA under section 515 of the Food Drug and Cosmetic Act (FDCA).

(c) September 29, 1995 - Date FDA approved PMA # P910062.

(11) The following is a brief description of the activities undertaken by applicant during the applicable regulatory review period.

30 JUN 89	VISX submits application to FDA for a new IDE for PTK to differentiate PTK from Photorefractive Keratectomy (PRK), which was the subject of IDE # G870181.
04 AUG 89	FDA approves 30 JUN 89 Application and assigns new IDE # G890122 to differentiate between PRK and PTK studies.
02 SEP 89	VISX sends copy of Study Outline to FDA.
11 SEP 89	VISX completes last Phase I treatment under the IDE # G870181
13 SEP 89	VISX contact report confirms teleconference with Richard Weiblinger that there are currently three sites approved for PTK, but only active site is Johns Hopkins and that VISX intends to expand to two additional sites by end of year. Ten patients treated to date, with an additional 30 patients may be treated under Phase II.
19 OCT 89	VISX submits request for Institutional Review Board (IRB) approval for Louisiana State University (LSU).
21 OCT 89	VISX submits supplement to FDA with Study Outline on ten patients plus protocol revisions based on statistical analysis (follow up every other day until re-epithelialization, initial evaluation from one week to one month), changes phases to submission of results at end of Phase II w/justification expand to Phase III with 150 patients at up to 10 sites; also submits Interim Statistical Report.
22 NOV 89	FDA approves 21 OCT 89 supplement.
22 NOV 89	VISX submits Protocol Amendment.
11 DEC 89	First Phase II treatment begins.

13 DEC 89	VISX submits IRB approval for Eye Foundation of Kansas City.
21 FEB 90	VISX submits supplement discussion of patient accrual problems, suggested solution, requests approval to expand to five sites in Phase II due to availability of only 3 sites.
23 MAR 90	FDA approves 21 FEB 90 supplement.
19 APR 90	VISX submits supplement with request for approval to treat a minor patient at LSU Eye Center (history of viral infection).
18 May 90	FDA conditionally approves 19 APR 90 supplement; study should be limited to patients with corneal thickness not thinner than 0.4mm in area of pathology; must amend protocol.
27 JUN 90	VISX submits supplement response to 18 May 90 conditional approval; "treatment is to be limited to patients whose final stromal thickness will be greater than 250 microns in the area of pathology".
28 JUN 90	VISX submits IRB approval for the Doheny Eye Institute, U. of Southern California at Los Angeles (Doheny).
11 JUL 90	VISX submits supplement for LSU IRB approval for treatment of minor patient.
17 JUL 90	VISX submits supplement for IRB approval for adding Genesee Valley Eye Care Center For Sight, Rochester, N.Y. (Rochester) as a clinical site.
26 JUL 90	VISX submits supplement with modifications to protocol and notifies FDA of intent to "file PMA when 100 patients in specific diagnostic group have been treated and followed as required by protocol."
27 JUL 90	FDA conditionally approves 27 JUN 90 supplement and requests justification for the "250 micron" submission.
01 AUG 90	VISX submits Model Change Report.
01 AUG 90	FDA approves 28 JUN 90 supplement for Doheny.
02 AUG 90	FDA approves 17 JUL 90 supplement for Rochester.

08 AUG 90	VISX submits reference copy of 26 JUL 90 supplement to R. Weiblinger at FDA.
08 AUG 90	VISX submits response to 27 JUL 90 conditionally approval with suggestion "limiting PTK procedure to patients who will have corneal thickness of not less than 250 microns post-treatment and provides justification."
10 AUG 90	FDA conditionally approves 11 JUL 90 supplement and certifies conditions required in 18 May 90 letter.
10 AUG 90	Last Phase II treatment completed.
16 AUG 90	VISX submits Preliminary Statistical Report for Phase II plus Medical Monitor evaluation and informs FDA that VISX "will begin Phase III using the presently approved protocol."
20 AUG 90	First Group 1 Phase III treatment begins at Wilmer Eye Institute at Johns Hopkins Hospital, Baltimore, MD.
22 AUG 90	VISX submits IRB approval for Manhattan Eye, Ear and Throat Hospital, N.Y., N.Y. (MEETH).
28 AUG 90	VISX submits notification to FDA that S. Michael Sharp is "official FDA correspondent."
30 AUG 90	FDA conditionally approves 26 JUL 90 supplement with limitation to 10 institutions and 200 subjects in Phase III. FDA requires report on retreated patients in Group 2 as failures and members of a discrete sub-group; other deficiencies on Case Report Forms (CRFs).
30 AUG 90	FDA acknowledges receipt of Model Change Report and assigns accession number 8910620.
07 SEP 90	FDA approves 08 AUG 90 submission.
21 SEP 90	First Group 2 Phase III treatment begins.
25 SEP 90	VISX submits supplement with response to FDA's request of 30 AUG 90.
23 OCT 90	VISX submits request to expand number of clinical sites to 15.
23 OCT 90	VISX submits Annual Report to FDA.

24 OCT 90	FDA approves 25 SEP 90 supplement.
05 NOV 90	VISX submits response to questions posed via phone by Paula Wilkerson at FDA re (1) patients with delayed re-epithelialization and (2) additional information re loss of 2 or more lines of best corrected visual acuity (BCVA), includes copies of Phase I and II studies.
21 NOV 90	FDA conditionally approves 23 OCT 90 submission and limits Phase III studies to 15 institutions and 200 patients. FDA requests clarification of corporate structure re: merger with Taunton and intent re: marketing approval.
27 NOV 90	Merger Taunton Technologies, Inc. (Taunton) and VISX, Incorporated (a California corporation). Taunton name changed to VISX, Incorporated.
03 DEC 90	VISX submits supplement with notification of change in corporate ownership and intent to pursue PMA approval for both excimer laser systems.
04 DEC 90	VISX submits supplement response to 21 NOV 90 conditional approval, clarifies corporate structure and requests up to a total of 40 sites.
04 JAN 91	FDA acknowledges receipt of 03 DEC and 04 DEC 90 supplements and discusses number of sites.
10 JAN 91	VISX submits desk copy to R. Phillips of FDA of 04 DEC 90 supplement.
28 JAN 91	VISX meets with FDA representatives to discuss PTK & PRK.
05 FEB 91	VISX submits response to 28 JAN 91 meeting with FDA, clarifies that the two systems are different and, therefore, should be allowed 20 systems each for clinical studies, and provides evidence as to difference.
08 MAR 91	FDA approves 05 FEB 91 request for a total of 20 VISX and 8 Taunton systems.
11 JUN 91	FDA advises VISX that annual report has not yet been received.
19 JUN 91	VISX submits list of clinical sites for Phase III studies.

24 JUN 91	VISX submits response to FDA (Jerome Dennis) re their 11 JUN 91 letter stating no annual report.
23 JUL 91	VISX submits 2 supplements with request for permission to expand indication for Group 2 patients to include those who have undergone previous corneal surgery (and therefore excluded from PRK protocol) and to specifically include patients who have had previous PRK.
05 AUG 91	VISX submits supplement request for permission to divide Group 2 patients into sub-groups (a) who had previous non-refractive surgery and (b) who had previous refractive corneal surgery.
07 AUG 91	VISX submits supplement request to withdraw 23 JUL 91 submission because "a similar supplement requesting permission to re-treat PTK patients under the PTK protocol is being made."
21 AUG 91	FDA acknowledges VISX withdrawal of 23 JUL 91 supplements.
29 AUG 91	VISX submits supplement request for permission to treat patient with bi-lateral recurrent corneal erosions at LSU.
06 SEP 91	FDA approves 05 AUG 91 supplement and limits investigation to 15 sites and 100 subjects in Group 1, and 150 subjects in Group 2.
27 SEP 91	FDA approves 29 AUG 91 supplement to treat LSU patient.
15 OCT 91	VISX submits Premarketing Approval (PMA) Application for Group 1.
16 OCT 91	FDA receives VISX's 15 OCT 91 Application and assigns it PMA Number P910062.
25 NOV 91	FDA advises VISX application incomplete and cannot be filed and provides list of deficiencies.

05 DEC 91	VISX submits request for permission to continue performing Group 1 @ rate of 20 eyes/site/year, stating that "The results of such additional cases will be included in all subsequent reports of the clinical evaluation of PTK which may be submitted to FDA."
13 DEC 91	VISX submits Amendment 1(A-1) and response to 25 NOV 91 deficiency letter.
18 DEC 91	VISX submits list of PTK Phase III clinical sites to FDA.
23 DEC 91	VISX submits A-2 and re-pagination of appendices with revised Table of Contents for P910062.
24 DEC 91	FDA approves 05 DEC 91 requests for 20 eyes/site per year limited to 15 sites while PMA under review.
20 JAN 92	Last Group 1 Phase III treatment completed.
28 JAN 92	VISX submits extra copy of final page of A-1 at request of Ming Shih at FDA.
29 JAN 92	VISX submits supplement request for permission to complete enrollment of patients in Group 2 with 20 patients/site/year.
18 FEB 92	VISX submits copies of PTK Protocol and Study Outline to W. Chiton at FDA.
18 FEB 92	FDA advises VISX that PMA application # P910062 is suitable for filing and notes deficiencies and requests response.
21 FEB 92	Last PTK Group 2 Phase III Treatment completed.
24 FEB 92	VISX sends bulletin to all PTK investigators saying additional data for PMA application needed and requesting that patients be brought in early for examination.
28 FEB 92	FDA approves 29 JAN 92 supplement regarding Group 2 treatments at 20 patients/site/year.

03 MAR 92	VISX submits A-3 responding to 18 FEB 92 deficiency letter that includes information on (1) contraindications and precautions in the Summary of Studies on safety and efficacy, (2) three patients hospitalized and (3) purpose of change of external venting system to an internal scrubber.
31 MAR 92	VISX submits A-4, six month update of clinical trials results, report of the clinical trial including updated information regarding the 112 patients included in the PMA cohort and data on an additional 47 patients who had not reached the three-month follow-up point at the time of data base closure for the original data analysis.
13 JUL 92	VISX submits response to teleconference with McCarthy and Weiblinger of FDA re the transfer of PTK Group 2 patients to separate IDE.
13 AUG 92	FDA assigned new IDE #G920142 to Group 2 patients in PTK study.
21 AUG 92	VISX submits semi-annual list of investigators to FDA.
02 SEP 92	FDA advises VISX that FDA has not received progress report from VISX.
03 SEP 92	VISX submits A-5, which provides additional clinical update covering 6 month period since the submission of the last clinical update.
14 SEP 92	FDA advises VISX that annual report had not been received.
06 OCT 92	VISX submits Annual Report in response to 14 SEP 92 letter.
18 NOV 92	VISX submits supplement request for permission to treat patients with anterior corneal scars, etc.
18 DEC 92	FDA conditionally approves 18 NOV 92 supplement.
07 JAN 93	Contact report between Dr. Knight and M. Rojas regarding deadline for BCVA listing.
09 MAR 93	VISX requests meeting with FDA to review status of PMA application #P910062.

23 MAR 93	VISX transmits floppy disks with data to Dr. Emma Knight at FDA for PMA #P910062.
30 MAR 93	VISX acknowledges phone call from Dennis McCarthy re update on status of PMA #P910062.
31 MAR 93	VISX advises Dr. Emma Knight VISX heard status from McCarthy.
16 APR 93	VISX submits comments to the FDA Ophthalmic Devices Advisory Panel.
30 JUN 93	VISX meets with FDA representatives.
07 JUL 93	VISX submits letter enumerating issues discussed during 30 JUN 93 meeting at FDA.
31 AUG 93	VISX submits A-6, responding to certain questions raised regarding the PMA during meeting of 30 JUN 93.
11 OCT 93	VISX submits to the FDA A-7 clinical update covering work done since the submission of the previous clinical update.
12 NOV 93	VISX Chairman, Charles Munnerlyn sends letter to FDA, addressing concerns re length of time to review PMA applications #P910062 and P930016.
14 DEC 93	Teleconference call with Emma Knight of FDA.
21 DEC 93	VISX submits A-8 responding to conference call 14 DEC 93 re questions and issues raised by Emma Knight. VISX authorizes the FDA to reference PMA #P930016 for the purpose of providing additional safety data to support the claims made in PMA #P910062.
22 DEC 93	VISX submits minutes of 14 DEC 93 teleconference and subsequent FDA-initiated phone calls.
23 DEC 93	VISX suggests meeting of VISX and FDA reps between 19 JAN and 22 JAN 94.
05 JAN 94	FDA acknowledges Charles Munnerlyn letter of 12 NOV 93 and advises possibility of review in March 1994.

06 JAN 94	VISX contact report detailing 06 JAN 94 teleconference with Dr. Knight.
12 JAN 94	VISX submits A-9 for PMA #910062 with CRFs for patients in PTK group 1 study and encloses Table of Contents, followed by a copy of patient listings from Amendment 8.
20 JAN 94	VISX submits A-10 in PMA #910062, summary of information regarding the Safety and Efficacy of the subject device, including alternative analyses. Included is data regarding the effect of excimer laser corneal ablation on the corneal epithelium.
02 FEB 94	VISX submits A-11 in response to inquiry from Reviewing Branch regarding possible modifications to the system: the PTK procedure utilizes separate software algorithms from PRK, all PTK studies used Model 2020B except Phase I patients treated at LSU and Wilmer. Modifications to system include: (1) effluent aspirator nozzle was relocated to avoid contact with patient during positioning (2) systems which were used in both the PRK and PRKa Clinical trials had the Astigmatic control module installed, along with the software to perform elliptical astigmatic/myopic ablations; (3) two systems used in Phase I were Model 2020A systems; they differed in externally vented rather than internal scrubbing and did not include astigmatic module; both units were modified in the field to include the astigmatic module and associated software but neither was converted to internal gas scrubbing.
23 FEB 94	VISX submitted to FDA 30 sets of copies of material to be reviewed by the FDA Ophthalmic Devices Advisory Panel, as requested by Dr. Emma Knight.
11 MAR 94	VISX submits notification to FDA that Mike Sharp is no longer VISX contact with FDA.
07 APR 94	Contact report of 07 APR 94 telephone conference of Ken Michael and Marti Rojas with Dr. Knight regarding PTK PMA #910062.
18 APR 94	FDA advises VISX that progress reports have not been received.
17 May 94	VISX submits confirmation to the FDA of the tradename change for "Twenty/Twenty".

17 May 94	VISX transmits dataline listing of pre and post-op visual acuity and change in spherical equivalency.
17 May 94	VISX notifies FDA regarding confirmation to change tradename.
27 May 94	VISX submits annual progress report in response to 18 04 94 letter re progress report.
08 JUN 94	FDA informs VISX that "PMA lacks information needed to determine whether there is reasonable assurance that the device is safe and effective for its intended use and" lists deficiencies.
30 JUN 94	FDA requests additional information on VISX's 27 May 94 annual progress report.
15 JUL 94	VISX submits to FDA Amendment to Software Validation/Operation manual.
17 AUG 94	VISX submits chronological calendar to FDA.
17 AUG 94	VISX submits amendment in response to 08 JUN 94 letter providing hazard analysis, software protocol, etc.
24 AUG 94	VISX submits request for extension to answer FDA's 30 JUN 94 letter.
29 AUG 94	VISX responds to questions 3 and 6 of 08 JUN 94 deficiency letter.
30 AUG 94	VISX submits Amendment to FDA's Office of Compliance and Surveillance (OCS) providing updated manufacturing section; identical to 24 AUG 94 submission for PMA #P930016.
02 SEP 94	VISX submits 7 copies of "an informational document regarding VISX's latest generation excimer laser, the Model C... to support equivalency of the Model B and Model C."
08 SEP 94	VISX submits supplemental response to FDA's 30 JUN 94 request.
08 SEP 94	VISX submits amendment to PMA #P910062 in response to 08 JUN 94 letter.
26 SEP 94	Contact report re: teleconf. with Q. Hoang at FDA.

27 SEP 94	Memo to Q. Hoang re: 26 SEP 94 teleconference.
05 OCT 94	FDA notifies VISX of temporary deferral of activities relating to medical device submissions.
06 OCT 94	FDA approves 08 SEP 94 supplement.
28 OCT 94	VISX notifies FDA of Alcon personnel authorized to represent VISX to FDA.
16 NOV 94	VISX sends communications to FDA to follow-up on VISX's 17 AUG 94 letter.
06 DEC 94	VISX communication confirms 06 DEC 94 teleconference with Q. Hoang concerning VisionKey® 4.10 software.
06 DEC 94	VISX communication confirms 06 DEC 94 teleconference with Terrance Clapham, S. Kalakerninos, and S. Crumpler.
15 DEC 94	VISX submits notification to FDA that Dr. Marguerite McDonald is no longer a VISX investigator.
16 DEC 94	VISX submits charts to FDA re IDE and protocol information.
04 JAN 95	VISX submits to Dr. Knight at FDA draft retreatment protocol.
09 JAN 95	VISX communication confirming 09 JAN 94 teleconference with Dr. Knight concerning hyperopia.
16 JAN 95	VISX submits notification to FDA that Marc Odrich has been appointed VISX Medical Monitor.
20 JAN 95	VISX submits notification to FDA of the appointment of Drs. Hailer and Odrich to VISX team.
27 JAN 95	VISX submits supplement to IDE#G890122.
02 FEB 95	VISX submits list of patients who underwent initial treatment outside of U.S. to FDA.
03 FEB 95	VISX sends response to 22 DEC 94 teleconference with T. Clapham and C. Robb.
08 FEB 95	VISX submits Retreatment Protocol.

08 FEB 95	VISX sends FDA amendment to PMA #P910062 referencing teleconference with Dr. Knight.
21 FEB 95	VISX submits notification to FDA of the removal of Dr. Steinert at Massachusetts Eye and Ear Infirmary as a VISX investigator.
02 MAR 95	FDA requests additional information on VISX's 27 JAN 95 supplement.
10 MAR 95	FDA disapproves 08 FEB 95 amendment.
14 MAR 95	FDA requests VISX data on nitrogen flow/no-flow.
06 APR 95	VISX submits request for permission to install VisionKey 4.10 software in specific clinical sites.
10 APR 95	VISX sends FDA twenty Panel Copies per Quyhn Hoang's request with changes.
13 APR 95	VISX sends FDA memo to Dr. Knight regarding all contact reports with FDA.
17 APR 95	VISX sends FDA disk copy of summary of Studies of Safety and Efficacy submission.
22 APR 95	VISX sends FDA revision of 13 APR 95 memo.
28 APR 95	Teleconference with FDA representative.
02 May 95	VISX submits notes on teleconference of 28 APR 95.
10 May 95	FDA submits response to VISX's 06 APR 95 proposal to install software.
30 May 95	VISX submits schedule to FDA to achieve regulatory compliance.
02 JUN 95	VISX submits update to 30 May 95 schedule to achieve regulatory compliance.
16 JUN 95	VISX submits update to 02 JUN 95 schedule to achieve regulatory compliance.

16 JUN 95	VISX submits confirmation of scheduled 26 JUL 95 meeting to discuss status of submissions and additional information required.
26 JUL 95	Mark Logan and Jordan Haller of VISX meet with FDA representatives.
29 SEP 95	FDA approves PMA #910062.

(12) In the opinion of Applicant, the patent is eligible for the requested extension.

The Regulatory Review Period - 35 USC 156(g)(3)(B)

The regulatory period started August 4, 1989, the day that the first IDE (#G890122) for PTK became effective; this was subsequent to the issuance of U.S. Patent 4,718,418 on January 12, 1988. The regulatory review period lasted 6 years, 1 month, 25 days (2,247 days, including one leap year in 1992) until approval on September 29, 1995.

The IDE Period - 35 USC 156(g)(3)(B)(i)

The period from the effective date of the first IDE (#G890122) on August 4, 1989 to the date of submission to the FDA of the first PMA (P910062) on October 15, 1991 is 2 years, 2 months, 11 days (802 days, with no leap year). Half of this period is 401 days.

The PMA Period - 35 USC 156(g)(1)(3)(ii)

The period from the date of submission to the FDA of PMA #P910062 on October 15, 1991 to the NDA approval on September 29, 1995 is 4 years, 11 months, 14 days (1,810 days, including 1 leap year).

Calculation of Extension - 35 USC 156(c)

The total sum of the possible extension is calculated as the sum of one half the IDE period (401 days) plus the full PMA period (1,810 days) for a total of 2,211 (6.1 years).

Normal Life of the Patent

Under 35 USC 154 (c)(1) the normal life of U.S. Patent 4,718,418 is the longer of (a) 20 years from the earliest U.S. priority date (November 17, 1983 + 20 = November 17, 2003) or (b) 17 years from the date of grant (January 12, 1988 + 17 = January 12, 2005). Thus, U.S. Patent 4,718,418 would normally expire on January 12, 2005 without the patent term extension.

Five Year Maximum Extension Applies

The maximum extension under 35 USC 156(g)(b)(A)) is five years. Therefore, Applicant requests the full five year period of 1,826 days, which includes a leap year, if applicable. With a five year patent term extension the expiration date of U.S. Patent 4,718,418 would be January 12, 2010.

The Full Extended Term Would Exceed Fourteen Years

Under 35 USC 156(c)(3), U.S. patent 4,718,418 cannot exceed a term extending beyond 14 years from the PMA approval date of September 29, 1995, namely September 29, 2009.

The Extension Request

Therefore, Applicant requests an extension of 4 years, 8 months, 17 days to extend the term of U.S. Patent 4,718,418 so that the Patent will expire September 29, 2009, if such request is granted.

(13) Applicant acknowledges the duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought herein.

(14) A check for the fee of $1,060.00 [37 CFR 1.20(j)] is attached.

(15) Inquiries and correspondence relating to this Application for Patent Term Extension should be directed to:

Tom M. Moran
Cooley Godward Castro Huddleson & Tatum
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155

(415) 843-5104 - Phone
(415) 857-0663 - Fax

(16) This Application for Patent Term Extension is being submitted in duplicate, certified as such below.

(17) The undersigned duly authorized agent of VISX hereby declares:

(a) that he is a patent attorney authorized to practice before the United States Patent and Trademark Office and has general authority from Applicant from the purpose of transacting all matters reasonably related to obtaining an extension of patent term

for U.S. Patent No. 4,718,418 and general authority to act on behalf of the Applicant in patent matters;

(b) that he has reviewed and understands the contents of this application being submitted pursuant to 35 USC 156;

(c) that he believes the patent is subject to extension pursuant to 37 CFR 1.710;

(d) that he believes an extension of the length claimed is justified under 35 USC 156 and the applicable regulations; and

(e) that he believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 CFR 1.720.

Respectfully submitted,

Date: Nov. 27, 1995

Tom M. Moran

Tom M. Moran
Reg. No. 26,314
Attorney for Applicant

This is to certify that the copy of this Application (together with the appended Attachments "A" and "B") filed herewith is a true and correct duplicate.

Date: Nov. 27, 1995

Tom M. Moran

Tom M. Moran

21009736

United States Patent [19]
L'Esperance, Jr.

[11] Patent Number: 4,718,418
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[54] APPARATUS FOR OPHTHALMOLOGICAL SURGERY

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[21] Appl. No.: 916,646

[22] Filed: Oct. 8, 1986

Related U.S. Application Data

[60] Continuation of Ser. No. 794,444, Nov. 4, 1985, abandoned, which is a division of Ser. No. 748,358, Jun. 24, 1985, abandoned, which is a continuation-in-part of Ser. No. 552,983, Nov. 17, 1983, abandoned.

[51] Int. Cl.[4] A61F 9/00; A61N 5/06; A61B 19/00

[52] U.S. Cl. ..... 128/303.1; 128/395; 219/121 L; 219/121 LA; 219/121 LH; 219/121 LQ; 219/121 LR; 219/121 LW; 364/413

[58] Field of Search ..... 128/303.1, 362, 395-398; 219/121 L, 121 LA, 121 LG, 121 LP, 121 LQ, 121 LU, 121 LV, 121 LW

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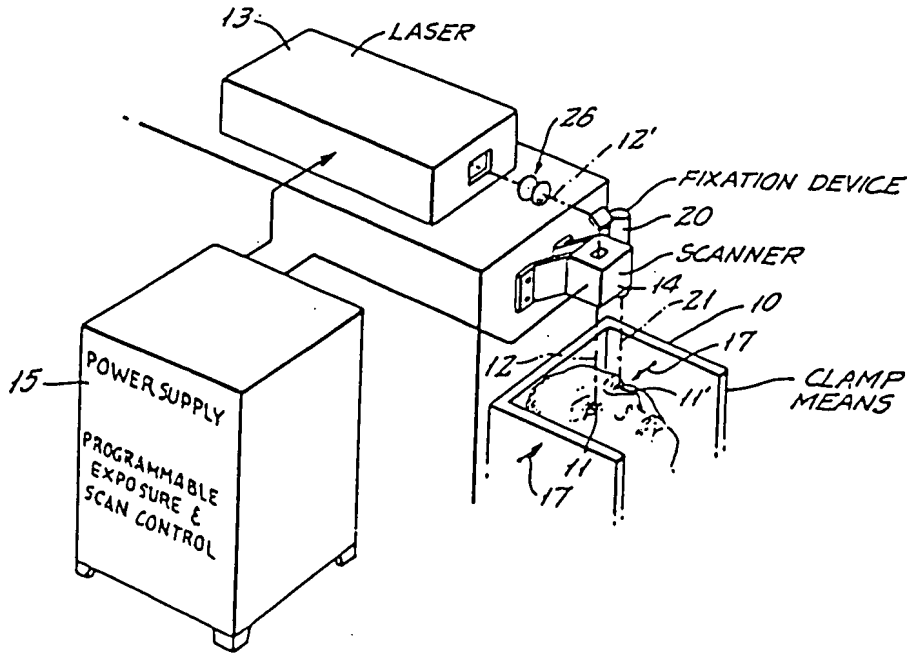
[57] ABSTRACT

The invention contemplates use of a scanning laser characterized by ultraviolet radiation to achieve controlled ablative photodecomposition of one or more selected regions of a cornea. Irradiated flux density and exposure time are so controlled as to achieve desired depth of the ablation, which is a local sculpturing step, and the scanning action is coordinated to achieve desired ultimate surface change in the cornea. The scanning may be so controlled as to change the front surface of the cornea from a greater to a lesser spherical curvature, or from a lesser to a greater spherical curvature, thus effecting reduction in a myopic or in a hyperopic condition, without resort to a contact or other corrective auxiliary lens technique, in that the cornea becomes the corrective lens. The scanning may also be so controlled as to reduce astigmatism and to perform the precise incisions of a keratotomy. Still further, the scanning may be so controlled as to excise corneal tissue uniformly over a precisely controlled area of the cornea for precision accommodation of a corneal transplant.

41 Claims, 16 Drawing Figures



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1	4,718,418	184	1930	----	06/914,646	01/12/88	10/08/86	08	NO	PAID

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